## United States Senate

March 17, 2022

The Honorable Joseph Biden President of the United States The White House 1600 Pennsylvania Avenue N.W. Washington, DC 20050

Dear President Biden,

The administration's unsatisfactory coordination of the health care supply chain is hampering access to lifesaving COVID antiviral medication. Federal taxpayers have funded the development and acquisition of twenty-three million courses of treatment pills, and it is imperative for the White House to get the federal bureaucracy on the same page so that Americans do not fall victim to mismanagement. I appreciate your prompt attention to the concerns raised in this letter.

While I understand the White House is advocating for more COVID funding,<sup>1</sup> management of current assets appears to be a pressing issue. With over twenty three million courses of antiviral pills already paid for and procured for use, we must remedy supply chain issues immediately.

In December 2021, the U.S. Food and Drug Administration (FDA) approved two COVID-19 antiviral treatment pills: Pfizer Inc.'s Paxlovid and Merck & Co.'s Molnupiravir. Federal taxpayers spent \$5.29 billion to secure ten million courses of Pfizer Paxlovid, and the government subsequently agreed to procure another ten million courses.<sup>2</sup> Taxpayers spent \$2.2 billion to buy 3.1 million courses of Merck's Molnupiravir.<sup>3</sup> Despite these significant procurements, it has been widely reported that these lifesaving drugs are hard to come by.<sup>4</sup> The

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<sup>&</sup>lt;sup>1</sup> White House Teleconference, March 15, 2022, "Background press call by Senior Administration Officials on COVID Response and Funding Needs," https://www.whitehouse.gov/briefing-room/press-briefings/2022/03/15/background-press-call-by-senior-administration-officials-on-covid-response-and-funding-needs/. *See also* A. Martinez, "The White House Says It's Running Out of Money to Cover COVID Tests and Vaccines," NPR, https://www.npr.org/transcripts/1086653838.

<sup>&</sup>lt;sup>2</sup> Manas Mishra, "U.S. to buy 10 mln courses of Pfizer's COVID-19 pill for \$5.3 biln," Reuters, Nov. 18, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/us-govt-buy-10-mln-courses-pfizers-covid-19-pill-529-bln-2021-11-18/. *See also* Pfizer press release, "Pfizer to Provide U.S. Government with an Additional 10 million Treatment Courses of its Oral Therapy to Help Combat COVID-19," Jan 4, 2022, https://www.pfizer.com/news/press-release/press-release-detail/pfizer-provide-us-government-additional-10-million.

<sup>&</sup>lt;sup>3</sup> Merck press release, "Merck and Ridgeback Announce U.S. Government to Purchase 1.4 Million Additional Courses of Molnupiravir, an Investigational Oral Antiviral Medicine, for the Treatment of Mild-to-Moderate Covid-19 in At Risk Adults," Nov. 9. 2021, https://www.merck.com/news/merck-and-ridgeback-announce-u-s-government-to-purchase-1-4-million-additional-courses-of-molnupiravir-an-investigational-oral-antiviral-medicine-for-the-treatment-of-mild-to-moderate-covid-19-in-a/. 
<sup>4</sup> Michael Ollove, "Lifesaving COVID Medications Can Be Hard to Come By," Stateline/Pew, Feb. 8, 2022, https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/02/08/lifesaving-covid-medications-can-be-hard-to-come-by. See also, Caitlin Owens, "It's very difficult to get access to antiviral COVID treatments," Axios, Jan. 29, 2022,

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problem does not appear to be the availability of pills, but rather a pipeline of delivery that is conflicted and in need of strong leadership.

Following the FDA's approval and procurement of such antiviral drugs, another portion of the administration informed pharmacies that dispensing fees for such drugs are not guaranteed, and that there should be no expectation for any uniform size of such fee. Guidance from the Centers for Medicare & Medicaid Services (CMS) made clear that while the provision of dispensing fees was encouraged, it was not required, and that dispensing fees associated with these lifesaving drugs would be left to controversial middle men in the insurance industry known as pharmacy benefit managers. Under federal law, pharmacy benefit managers set fees for Medicare beneficiaries who get pills under the Part D benefit. As a result, multiple media outlets are reporting that access to the taxpayer financed drugs is in jeopardy. Pharmacists are now questioning whether or not they will provide COVID antiviral pills given the debate over dispensing fee amounts.

At the same time, the Department of Health and Human Services (HHS) announced a new initiative that, importantly, will streamline the provision of antiviral pills to people by distributing the pills directly to pharmacies—but this new initiative is only working with certain pharmacies. In March 2022, HHS launched the "Test to Treat" initiative. Under the initial program, CVS Minute Clinics will receive the pills directly from the U.S. government, rather than states, and take steps to write prescriptions for people who come in and test positive to give them the pills right away. The timely provision of COVID antiviral pills is critical, as such pills are most effective at reducing the risk of hospitalization when started within five days of symptom onset. However, it appears the initial *Test to Treat* initiative is excluding numerous pharmacies, including independent pharmacies and non-clinics. The *Test to Treat* initiative also comes at a time when, as previously mentioned, pharmacists are threatening to quit dispensing the pills at all.

compete for access," ABC News, Jan. 29, 2022, https://abcnews.go.com/Politics/promising-covid-19-antiviral-pill-scarce-supply-doctors/story?id=82542422.

<sup>&</sup>lt;sup>5</sup> Center for Medicare & Medicaid Services, Memo to All Part D Sponsors from CMS Administrator Chiquita Brooks-LaSure, Nov. 23, 2021, https://www.cms.gov/files/document/oralantiviralguidance11232021.pdf.

<sup>&</sup>lt;sup>6</sup> Bob Herman, "Pharmacies feel stiffed on COVID pill payments," Axios, Feb. 7, 2022, https://www.axios.com/pharmacies-feel-stiffed-covid-pill-payments-596dac54-eda6-4eca-aa04-4bf424df18c3.html.

<sup>&</sup>lt;sup>7</sup> Celine Castronuovo, "Covid Pill Dispensing Costs Push Pharmacies to Call on Medicare," Bloomberg Law, Jan. 31, 2022, <a href="https://news.bloomberglaw.com/health-law-and-business/covid-pill-dispensing-costs-push-pharmacies-to-call-on-medicare.">https://news.bloomberglaw.com/health-law-and-business/covid-pill-dispensing-costs-push-pharmacies-to-call-on-medicare.</a> See also, Jared Hopkins, "Covid-19 Pill Access at Risk as Pharmacies Push for Bigger Payments," The Wall Street Journal, Feb. 20, 2022, <a href="https://www.wsj.com/articles/covid-19-pill-access-at-risk-as-pharmacies-push-for-bigger-payments-11645365601">https://www.wsj.com/articles/covid-19-pill-access-at-risk-as-pharmacies-push-for-bigger-payments-11645365601</a>. See also, Bob Herman, "Pharmacies feel stiffed on COVID Pill payments," Axios, Feb. 7, 2022, <a href="https://www.axios.com/pharmacies-feel-stiffed-covid-pill-payments-596dac54-eda6-4eca-aa04-4bf424df18c3.html">https://www.axios.com/pharmacies-feel-stiffed-covid-pill-payments-596dac54-eda6-4eca-aa04-4bf424df18c3.html</a>.

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Annuarie Timmins, "Pharmacy and health organizations see problems with 'Test to Treat' program," New Hampshire Bulletin, March 16, 2022, https://newhampshirebulletin.com/2022/03/16/pharmacy-and-health-organizations-see-problems-with-test-to-treat-program/.

<sup>&</sup>lt;sup>10</sup> U.S. Department of Health and Human Services press release, "Fact Sheet: Biden Administration Launches Nationwide Test-to-Treat Initiative Ensuring Rapid on the Spot' Access to Lifesaving COVID Treatments," March 8, 2022, <a href="https://www.hhs.gov/about/news/2022/03/08/fact-sheet-biden-administration-launches-nationwide-test-treat-initiative-ensuring-rapid-on-spot-access-lifesaving-covid-treatments.html">https://www.hhs.gov/about/news/2022/03/08/fact-sheet-biden-administration-launches-nationwide-test-treat-initiative-ensuring-rapid-on-spot-access-lifesaving-covid-treatments.html</a>.

<sup>11</sup> Ibid. See also Timmins.

<sup>&</sup>lt;sup>12</sup> See Timmins.

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Further, additional controversy rages over whether or not pharmacists *should be able to* prescribe COVID antivirals, or if prescribing should be the sole domain of medical professionals. While some argue that pharmacists, who have access to complete prescription records of patients, are best positioned to get lifesaving drugs to patients quickly, others argue that prescribing drugs should be left to the doctors that work most closely with the patients.<sup>13</sup>

The nation is rightfully proud of Operation Warp Speed and other public-private partnership successes that have led to life-saving vaccines and treatments throughout the course of this pandemic. We cannot let the federal bureaucracy, or the health care bureaucracy, stand in the way of access to drugs that Americans both need and financed.

In closing, I urge you to ensure all agencies and subcomponents have the support needed to ensure maximum access to COVID antiviral medications. I stand willing to assist you in this pursuit. Thank you again for your consideration of this matter.

Sincerely,

Mike Braun U.S. Senator

Mike Braun

<sup>13</sup> Ibid.